

REMARKS

For reference, pages 2 and following of the Office Action are set forth below with Applicants remarks interspersed:

Application/Control Number: 10/057,270 Art Unit: 1631

DETAILED ACTION

Applicant's arguments, filed 3/11/2009, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Page 2 Applicants have amended their claims, filed 3/11/2009, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant has newly added claims 39-46 in the response filed 3/11/2009, which have been acknowledged and entered.

Applicant's cancellation of claims 25-27 in the response filed 3/11/2009 is acknowledged.

Claims 4-10, 19, 21, 23, 24, 28-29, and 39-46 are the current claims hereby under examination.

The following rejections are being newly applied, which have been necessitated by amendment:

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-10, 19, 21, 23, 24, 28-29, and 39-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 4 and 40 and all claims dependent therefrom comprise step C, wherein the amendment "computationally fragmenting each target nucleic acid sequence so as to create a subsequence database of nucleic acid subsequences of length N" has been deemed as new matter. Applicant has pointed to page 18, lines 33-37 for support for said computationally fragmenting, wherein support has not been found. Said page 18, lines 33-37 refers to the program probes hash table generator, which appears to operate on specific type of sequences, i.e. 16s rRNA sequences, which it then excises oligonucleotides of specified length, wherein the amended

claim step is directed to computation by fragmenting any type of target nucleic acid sequence, which may or may not include 16s rRNA sequences. Therefore, the amended claim step does not appear to have support where pointed to by applicant.

"Fragmenting" is discussed at pages 2, 30, 32 and 33 and the Applicants provide programs which enable such fragmenting to be accomplished by computer. It is urged that those skilled in the art will be enabled to thus accomplish "computationally fragmenting each target nucleic acid sequence so as to create a subsequence database of nucleic acid subsequences of length N", by their reading of the 16S exemplified at Page 18. This reflects the fact that the procedure will be the same for any nucleic acid containing four distinct bases, e.g. guanosine, cytosine, adenine, and either uracil or thymidine.

To respond to the objection, Applicants' have marked step C of claim 4 and claim 40 to be an optional step. Step C can simplify the calculation indicated at page 6 lines 15-16 wherein a signature quality function is to be calculated for every possible sequence of length N (N-mers). Any N-mer that never occurs in any of the sequences being used in the nucleic acid sequence database of step A will obviously have no utility because that N-mer will not be a signature of anything. Likewise, if a sequence occurs in exactly one of the sequences it provides no useful grouping information and is not useful. Thus, there is no need to include these sequences. This is pointed out in the specification on page 6 lines 16-20. Optional Step C provides a way of removing these uninteresting subsequences by fragmenting the sequences that are being used and keeping track of how many times each subsequence of length N actually occurs. Those subsequences of length N that do not occur in the target

sequence from at least two different organisms are removed from further consideration. In the absence of step C, step D of claims 4 and 40 must instead consider all possible subsequences of length N. Although done the same way, the calculation is then much more protracted and tedious.

**Claim Rejections - 35 USC § 112-Second Paragraph
Response to Arguments**

Applicant's arguments, filed 3/11/2009, with respect to the rejections of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's amendments to the claims. Therefore the rejections have been withdrawn.

The Examiner is thanked for withdrawing the 35 USC 112 second paragraph rejections.

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The following rejections are being newly applied, which have been necessitated by amendment:

The following is a quotation of the second paragraph of 35 U.S.C. 112: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-10, 19, 21, 23, 24, 28-29, 39-44, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 40 (and all claims dependent therefrom), step D, recites the wording "creating a signature database," wherein what comprises the "signature database" has been deemed as vague and indefinite. Step D, describes creating a database, but only discloses a method step for performing a calculation, i.e. "tabulating the extent to which the presence of each particular nucleic acid subsequence of length N in the subsequence database is characteristic of each node in the bifurcating phylogenetic tree of genetic relationship by examining the occurrence frequency of each subsequence in the target nucleic acid of the organisms and viruses encompassed by or not encompassed by each node in the tree." Therefore, it is unclear as to what data comprises the "signature database" with regards to the calculated characteristics of each nucleic acid subsequence. Clarification via clearer claim wording is required.

Claim 4 (and all claims dependent therefrom),

Claim 4 Step D now recites “of characteristic signature sequences” to make clear the content of the “signature database” and to provide antecedent basis for the Step E recitation “of characteristic signature sequences”.

Step E recites the limitation

“the signature database of characteristic signature sequences” in lines 1-2 of step E. The wording appears to refer back to the signature database created in step D, wherein the database does not appear to be comprised of “signature sequences.” The signature

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database created in step D only appears to be comprised of tabulated characteristics, which are based on an occurrence frequency. There is no recitation in step D of a signature database comprised of “signature sequences.” Therefore, there is insufficient antecedent basis for this limitation in the claim.

Claim 4 Step D now recites “of characteristic signature sequences” to make clear the content of the “signature database” and to provide antecedent basis for the Step E recitation “of characteristic signature sequences”.

Claim 40 (and all claims dependent therefrom), step E, has been deemed as vague and indefinite. It is unclear as to how signature probes are derived from a signature database, wherein it is unclear as to what data comprises the signature database. Therefore, it is unclear as to how to further derive signature probes from a database wherein it is unclear as to what data comprises the signature database. Clarification via clearer claim wording is required.

Claim 4 Step D now recites “of characteristic signature sequences” to make clear the content of the “signature database” and to provide antecedent basis for the Step E recitation “of characteristic signature sequences”.

Claim 40 (and all claims dependent therefrom), step E, has been deemed

The following rejections are being newly applied, which have been necessitated by amendment:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 40 and 45 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter.

Claims 40 and 45 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

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In the instant case, the claims are drawn to a method of determining the genetic affinity of organisms or viruses in a test sample. The recited process involves the abstract and computational steps of creating databases, computationally fragmenting target nucleic acid sequences, and deriving a plurality of signature probes from the signature database. As such, the instant claims do not recite any to a particular machine or apparatus, nor do the instant claims involve a transformation of a particular article. The final step of deriving a plurality of signature probes has been interpreted as reading on computationally deriving a plurality of signature probes, wherein the step is not necessarily carried out in the physical realm. Therefore, the instant claims are drawn only to an abstract process that only manipulates data and, therefore, are not directed to statutory subject matter.

The claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter (In re Grams 12 USPQ2d 1824 Fed. Cir. 1989). Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. The applicants are cautioned against introduction of new matter in an amendment.

Steps C and D of Claims 4 and 40 now recite "in a programmed computer" to specify the use of a machine in the steps, and to distinguish the invention from unstatutory mental steps. The use of a computer has always been implicit in the claims and in the specification e.g. at Program Code Appendix on page 1, Figure 5, and Table E, etc. and these

amendments merely make the computer explicit in the Claims.

Claim Rejections - 35 USC § 102

Response to Arguments

Page 7 Applicant's arguments, filed 3/11/2009, with respect to the rejection of claims have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejection has been withdrawn.

The Examiner is thanked for withdrawing the 35 USC §102 rejections.

Conclusion

No claim is allowed.

Applicants have discovered and taught for the first time in this Application, a valuable diagnostic process which is able to determine the genetic affinity of an unknown organism in the context of previously studied organisms without prior knowledge of what will be present. Moreover, the invention can determine the genetic affinity of N different organisms with less than N probes. Prior Art classical methods require at least as many probes as organisms-to-be-identified.

The rejections on prior art having been withdrawn and the formal rejections having each been addressed above, allowance of the Claims as now presented is earnestly solicited under the mandate of 35 U.S.C. 101.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicants are responding within two months of the Final Action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-2727540.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.QOv>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ Jason Sims /

/ Michael Borin /

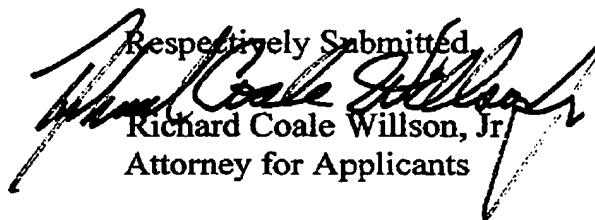
Primary Examiner, Art Unit 1631

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The Amendments herein are merely clarifying wording and no estoppel or new matter is involved; they are not required to distinguish from prior art.

Any necessary (small entity) charges can be charged to USPTO Deposit Account 200336 of Technology Licensing Co. LLC. Correspondence may be addressed to Customer No. 26830.

The Examiner is especially invited to telephone Applicants' Attorney if that would expedite prosecution and disposal of this Application.

Respectively Submitted

Richard Coale Willson, Jr.
Attorney for Applicants

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Overview & Itinerary | Staterooms | Deck Plans | Food & Dining | Entertainment & Activities | Photo Gallery | Reviews

Highlights:

- The Ryndam is a past customer favorite!
- The Pinnacle Grill offers an elegant, sophisticated dining experience that features premium beef, seafood dishes and an extensive wine list.
- Explorations Café features the largest library at sea as well as comfortable music listening stations and Internet access.
- Past guests rave about the quality of the spa, inviting library and scrumptious cuisine served by attentive staff.

Cruise Itinerary:

Day	Ports of Call	Arrival	Departure
1	Vancouver (Canada Place), British Columbia	---	5:00 p.m.
2	Victoria, British Columbia	7:00 a.m.	1:00 p.m.
3	At Sea	---	---
4	At Sea	---	---
5	San Diego, California	8:00 a.m.	5:00 p.m.
6	At Sea	---	---
7	Cabo San Lucas, Mexico	12:00 p.m.	6:00 p.m.

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